

REMARKS

Applicant has received and carefully reviewed the Office Action of October 9, 2007.

Applicant has amended claims 1-4, 6-21, 23-24, 26-29, and cancelled claim 5, in order to further refine and clarify that which the Applicant regards as the claimed invention. Support for the amendments can be found throughout the specification, and in particular, on pages 8 and 12. No new matter has been added by these amendments.

Rejection under 35 U.S.C. §102(b)

The Examiner rejected claims 27-29, under 35 U.S.C. §102(b), as anticipated by Nilsson (WO 91/00074). According to the Examiner, Nilsson teaches a kit comprising a device for urinary catheterization and a pharmaceutically active composition comprising a hormone for insertion into a female urethra. Applicant respectfully traverses this rejection.

Nilsson discloses an in-dwelling catheter adapted for long-term use. The catheter is specifically designed to fit into the female urethra, and to be inserted in the urethra with collars

that are located between the musculature surrounding the urethra. The conical end or collar 14 of said catheter, abuts against the wall of the urethra to seal it. Another collar 16 is located distally and is angled in the opposite direction from collar 14, so as to stay in the desired position (Nilsson at pages 8-10) even with normal movement of the user. Applicant's catheter has no such collars, and is adapted for intermittent use. In fact, the catheter of Nilsson is provided with a valve so that the user can turn off the flow of urine in order to allow the bladder to become filled. This feature allows the muscles of urethra, or urinary tract of the user, to be exercised by the user, and therefore strengthens the muscles of the urethra to prevent incontinence (Nilsson at page 5). The catheter of Nilsson is also provided with a means of disconnecting the drain tube and collection reservoir from the in-dwelling portion of the catheter. Applicant's claimed invention has none of these features.

Nilsson allegedly teaches that the hollow conical part 14 may accommodate a viscous fluid such as a hormone preparation (page 8, lines 3-6), and in the rejection, the Examiner cites Nilsson for teaching a catheter having a pharmaceutically active composition disposed therein. Nilsson teaches that the contents of the conical

portion are dispensed only when the user moves from a sitting to a standing position, or other normal movements (Nilsson at page 10). The hormone is allegedly delivered by pressure of the musculature which will cause the drug to permeate out of the walls of the conical portion 14. Applicant submits that Nilsson fails to teach, or identify, what type of hormone would be contained within the catheter, and for what purpose. Furthermore, there is no teaching in Nilsson as to why the preparation must be in a viscous fluid state, or how the fluid would be included in the space. Nilsson also fails to teach any dosage range for inclusion of the proposed hormone preparation.

In contrast, Applicant's claimed invention comprises a catheter adapted for intermittent use, and also having a pharmaceutically active composition comprising at least one agent selected from the group consisting of hormones, efferent blocking agents, afferent blocking agents and sympathomimetic agents, said composition provided on the outer surface of the catheter so that delivery of the composition to the urethra is direct, and complete in a relatively short time (e.g. minutes).

"In order to render a claimed apparatus or method obvious, the prior art must enable one skilled in the art to make

and use the apparatus or method." Rockwell International Corp. v. United States, 147 F.3d 1358, 47 USPQ2d 1027, 1032 (Fed. Cir. 1998). Applicant respectfully submits that Nilsson is not enabling under 35 U.S.C. §112, first paragraph, for teaching a catheter having a pharmaceutical composition disposed therein, and capable of delivering said composition to the urethra of a patient. In view of Applicant's amended claims, Nilsson also does not teach a catheter adapted for intermittent use. Nilsson, therefore, does not teach each and every element of Applicant's claimed invention, and therefore cannot anticipate claims 27-29 as amended. Applicant respectfully requests withdrawal of this rejection.

Rejection under 35 U.S.C. §103(a)

The Examiner rejected claims 1-14, and 21-26 as unpatentable over Nilsson, in view of WO 02/24246 to Hunter. Nilsson is offered by the Examiner for teaching a catheter comprising a pharmaceutical composition. The Examiner admits, however, that Nilsson does not teach a catheter with a pharmaceutically active composition being located on the outer surface of the catheter. Hunter is therefore offered by the Examiner for teaching a catheter having pharmaceutically active composition (antimicrobial) on the outer surface of the catheter.

As such, the Examiner alleges that it would have been obvious to one of ordinary skill in the art to provide the pharmaceutically active composition on the outer surface of the catheter of Nilsson, because Hunter teaches the predictable result of a pharmaceutically active composition being delivered to the user, when said composition is on the outer surface of the catheter. Applicant respectfully traverses this rejection.

Applicant submits that, as stated above with regard to the rejection under §102, Nilsson is not enabling under 35 U.S.C. §112, first paragraph, for teaching a catheter having a pharmaceutical composition disposed therein, and is therefore incapable of delivery of said composition to the urethra of a patient. Nilsson teaches a catheter apparatus that is designed to be retained by the incontinent patient (in-dwelling). The catheter has a means of shutting off the flow of urine so that the bladder becomes filled, and allows the patient the sensation of a filled bladder. The patient is then supposed to exercise the appropriate bladder muscles in order to improve continence before voiding the bladder into the attached reservoir. There is no teaching or suggestion in Nilsson of the use of any drugs or pharmaceutical compositions that would treat patients with incontinence. Nilsson

contains a single paragraph which states that the conical part 14 may be filled with a hormone without any description on how this is to be performed. Moreover, there is no further teaching of what that substance would or should be or at what concentration. Further Nilsson teaches that the hormone could be released with squeezing or pressure on the conical part 14, yet it does not explain how the hormone can leave without any leakage of urine into or out of the conical part. As such, Applicant submits that Nilsson can only be properly considered prior art for teaching an in-dwelling catheter suitable for use in improving bladder muscle tone in incontinent patients.

In addition, contrary to the Examiner's assertion, there is no teaching in Nilsson for providing a catheter adapted for intermittent use. Page 10, lines 27-32 of Nilsson only teach that the catheter can either be fixed or detachably connected to the drainage hose. This is a feature of in-dwelling catheters. Nowhere in the specification of Nilsson is there any mention of intermittent use.

Hunter is offered by the Examiner for teaching that a pharmaceutically active composition can be located on the outer surface of a urinary catheter. Hunter actually teaches a catheter

having an external surface coated with a mixture of hydrophilic polymer (lubricant) and an antimicrobial compound, along with other anti-inflammatory agents, soaps, or anti-oxidants to prevent urinary tract infection. Hunter does not teach any of the pharmaceutical compositions as claimed by Applicants. This is because Hunter is not directed to pharmacological treatment of urinary incontinence or overactive bladder contraction. Hunter is directed to reducing the risk of urinary tract infection and inflammation due to catheterization. There is no teaching or suggestion in Hunter, for treating incontinence in a patient, by delivering the compositions disclosed by Applicant, such as estrogens or substances that block parasympathetic nervous activity and related nerves, by applying said composition onto the outer surface of an intermittent catheter such that the composition is delivered to the urinary tract of a patient during catheterization.

Applicant submits that the Examiner has failed to establish a *prima facie* case of obviousness with regard to the rejected claims, because the combination of Nilsson in view of Hunter, does not teach each and every element of Applicant's claimed invention. Furthermore, the combination of Nilsson in view of Hunter does not provide any motivation to make an intermittent

catheter for use in incontinent patients having a pharmaceutically active composition comprising at least one agent selected from the group consisting of hormones, efferent blocking agents, afferent blocking agents and sympathomimetic agents, wherein said catheter is adapted to deliver the composition in the lower urinary tract system during catheterization.

Applicant states that the combination of references made by the Examiner is not sufficient to render Applicant's claimed invention obvious, under the rationales for support of rejections under 35 U.S.C. §103(a), according to the USPTO Examination Guidelines for determining obviousness under 35 U.S.C. §103, in view of the U.S. Supreme Court Decision in KSR International Co. v. Teleflex, Inc., 82 USPQ2d 1385 (2007).

In particular, the combination of prior art elements does not correspond to either rationale 1 or 2): combining prior art elements according to known methods to yield predictable results, or simple substitution of same. Nilsson teaches an in-dwelling catheter adapted so that patients can exercise their bladder muscles and become less incontinent. Hunter teaches that intermittent catheters can be coated with antimicrobial compositions to prevent urinary tract infections. Neither

reference, however, teaches treatment of incontinence with a pharmaceutically active composition comprising at least one agent selected from the group consisting of hormones, efferent blocking agents, afferent blocking agents and sympathomimetic agents. In addition, neither reference teaches that the catheter is adapted to deliver said pharmaceutically active composition in the lower urinary tract during catheterization. Therefore, there is no teaching or suggestion in the cited references that would allow one of ordinary skill to have a reasonable expectation of success. Applicant submits further, that there could also be no simple substitution by one of ordinary skill without the teachings of proper dosages and formulations that would be effective in the urethra for incontinence.

With regard to rationales 3 and 4 in the KSR guidelines, Applicant points out that the Examiner has not provided any evidence that prior to Applicant's claimed invention, there existed any known techniques for treating incontinence or hyperactive bladder using Applicant's claimed compositions via administration directly into the urethra. Moreover, while Hunter teaches prevention of urinary tract infection via application of antimicrobial agents onto a catheter, antimicrobial prophylaxis

with anti-infective drugs was well known.

With regard to rationale 5 of the KSR guidelines, Applicant submits that Applicant's claimed invention could not be considered by one of ordinary skill to have been obvious to try, because previously, all the pharmaceutical compositions claimed by Applicant for use in treating hyperactive bladder or incontinence, were administered systemically, intra-vaginally, or in the bladder itself. Finally, the remaining rationales 6 and 7 of the KSR guidelines do not apply, because there was no teaching suggestion or motivation in the prior art for one of ordinary skill to combine the cited references to arrive at Applicant's claimed features, other than those found in Applicant's own disclosure.

In view of the foregoing, Applicant submits that the combination of teachings of Nilsson, in view of Hunter, cannot render Applicant's claimed invention *prima facie* obvious, and respectfully requests withdrawal of this rejection.

Claims 15-17 were rejected under 35 USC §103(a) as unpatentable over Nilsson, in view of Hunter, and further in view of Martan et al. (Ceska Gynekol, Jan. 1999). According to the Examiner, the combination of Nilsson in view of Hunter teaches all

aspects of these claims except the hormone being estriol or estrogen. Martan et al. teach the use of estrogen intra-vaginally for the treatment of incontinence in women. The Examiner states that it would have been obvious to one of ordinary skill to use estriol or estrogen as the hormone in the device of Nilsson. Applicant respectfully traverses this rejection.

As Applicant has stated above, the combination of the teachings of Nilsson, in view of Hunter, fails to teach each and every element of Applicant's claimed invention, and does not provide any motivation to make Applicant's intermittent catheter having a pharmaceutically active composition, and wherein said catheter is adapted to deliver said pharmaceutically active composition in the lower urinary tract system during catheterization. This failure to teach all of Applicant's claimed features is not cured by the addition of Martan et al. As such, Applicant submits that the combination of teachings of Nilsson in view of Hunter and Martan et al. cannot render Applicant's claimed invention *prima facie* obvious, and respectfully requests withdrawal of this rejection.

Claims 18-20 were also rejected under 35 USC §103(a) as unpatentable over Nilsson, in view of Hunter, and further in view

of USP 6,039,967 to Ottoboni et al. According to the Examiner, the combination of Nilsson in view of Hunter teaches all aspects of these claims except the use of oxybutynin. Ottoboni et al. is offered for teaching the treatment of incontinence by delivering to the urinary tract, a catheter coated with the composition. The Examiner states that it would have been obvious to one of ordinary skill to use oxybutynin as the pharmaceutically active composition as taught in Ottoboni et al. in the device of Nilsson. Applicant respectfully traverses this rejection.

As Applicant has stated previously, the combination of the teachings of Nilsson in view of Hunter, fails to teach each and every element of Applicant's claimed invention, and does not provide any motivation to make an intermittent catheter for use in incontinent patients having a pharmaceutically active composition comprising at least one agent selected from the group consisting of hormones, efferent blocking agents, afferent blocking agents and sympathomimetic agents, and said catheter being adapted to deliver said pharmaceutically active composition in the lower urinary tract during catheterization. This failure to teach all of Applicant's claimed features is not cured by the addition of Ottoboni et al.

Ottoboni et al. do not teach treatment of incontinence by

delivering oxybutinin to the lower urinary tract by the urethra. Rather, Ottoboni et al. teaches the placement of a sustained release formulation of a composition directly into the bladder, where the composition can be released. There is no teaching or suggestion of intra-urethral delivery of compositions via a catheter. As such, Applicant submits that the combination of teachings of Nilsson in view of Hunter and Ottoboni et al. cannot render Applicant's claimed invention *prima facie* obvious, and respectfully requests withdrawal of this rejection.

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all currently outstanding rejections, and that they be withdrawn. As such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

If the remittance herewith is incorrect in any fashion, kindly debit or credit Deposit Account No. 06/1358 appropriately and advise the undersigned accordingly.

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Respectfully submitted,

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